

TABLE 1—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN<sup>1</sup>

21 CFR section/activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
701.3—Ingredients in order of predominance .....	1,518	21	31,878	1	31,878
701.11—Statement of identity .....	1,518	24	36,432	1	36,432
701.12—Name and place of business .....	1,518	24	36,432	1	36,432
701.13—Net quantity of contents .....	1,518	24	36,432	1	36,432
Total .....	.....	.....	.....	.....	141,174

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The hour burden is the additional or incremental time that establishments need to design and print labeling that includes the following required elements: A declaration of ingredients in decreasing order of predominance, a statement of the identity of the product, a specification of the name and place of business of the establishment, and a declaration of the net quantity of contents. These requirements increase the time establishments need to design labels because they increase the number of label elements that establishments must take into account when designing labels. These requirements do not generate any recurring burden per label because establishments must already print and affix labels to cosmetic products as part of normal business practices.

The estimated annual third party disclosure is based on data available to the Agency, our knowledge of and experience with cosmetic labeling, and our communications with industry. We estimate there are 1,518 cosmetic product establishments in the United States. We calculate label design costs based on stock keeping units (SKUs) because each SKU has a unique product label. Based on data available to the Agency and on communications with industry, we estimate that cosmetic establishments will offer 94,800 SKUs for retail sale in 2017. This corresponds to an average of 62 SKUs per establishment.

One of the four provisions that we discuss in this information collection, § 701.3, applies only to cosmetic products offered for retail sale. However, the other three provisions, §§ 701.11, 701.12, and 701.13, apply to all cosmetic products, including non-retail professional-use-only products. We estimate that including professional-use-only cosmetic products increases the total number of SKUs by 15 percent to 109,020. This corresponds to an average of 72 SKUs per establishment.

Finally, based on the Agency's experience with other products, we estimate that cosmetic establishments

may redesign up to one-third of SKUs per year. Therefore, we estimate that the number of disclosures per respondent will be 21 (31,878 SKUs) for § 701.3 and 24 each (36,432 SKUs) for §§ 701.11, 701.12, and 701.13.

We estimate that each of the required label elements may add approximately 1 hour to the label design process. We base this estimate on the hour burdens the Agency has previously estimated for food, drug, and medical device labeling and on the Agency's knowledge of cosmetic labeling. Therefore, we estimate that the total hour burden on members of the public for this information collection is 141,174 hours per year.

Dated: May 18, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-D-0349]

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Providing Waiver-Related Materials in Accordance With the Guidance for Industry on Providing Post-Market Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed

extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information associated with the Guidance "Providing Post-market Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report)."

**DATES:** Submit either electronic or written comments on the collection of information by July 24, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 24, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of July 24, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you

do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2013-D-0349 for “Providing Waiver-Related Materials in Accordance With the Guidance for Industry on Providing Post-market Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format.” Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other

applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

#### Providing Waiver-Related Materials in Accordance With the Guidance for Industry on Providing Post-Market Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format (Periodic Benefit-Risk Evaluation Report), OMB Control Number 0910-0771—Extension

The International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use issued, on November 15, 2012, the ICH harmonized tripartite guideline entitled “Periodic Benefit-Risk Evaluation Report (PBRER) E2C(R2)” (the PBRER guideline) (available at <http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html>). The PBRER guideline is intended to promote a consistent approach to periodic post-marketing safety reporting among the ICH regions and to enhance efficiency by reducing the number of reports generated for submission to the regulatory authorities. The PBRER is intended to provide a common standard for periodic reporting on approved drugs or biologics among the ICH regions.

FDA currently has OMB approval for the required submission of periodic adverse drug experience reports (PADER) for drugs subject to a new drug application (NDA) or an abbreviated new drug application (ANDA) (§ 314.80(c)(2) (21 CFR 314.80(c)(2)) (OMB control number 0910-0230), and for the required submission of periodic adverse experience reports (PAER) for drugs subject to a biologics license application (BLA) (§ 600.80(c)(2) (21 CFR 600.80(c)(2)) (OMB control number 0910-0308).

There is considerable overlap in the information required under §§ 314.80(c)(2) and 600.80(c)(2) and the information requested in a periodic safety report using the ICH E2C(R2) PBRER format. Applicants subject to periodic safety reporting requirements under FDA regulations could choose to continue to submit the reports as specified in those regulations, and would be permitted to submit reports in the PBRER format and submit reports as specified in FDA regulations with an approved waiver. Companies who submit periodic reports on the same drug to multiple regulators, including not only the United States, but, also the European Union, Japan, and regulators in other countries who have elected to adopt the ICH standards, may find it in their interest to prepare a single PBRER,

rather than preparing multiple types of reports for multiple regulators. As a result, FDA, in the **Federal Register** of November 29, 2016 (81 FR 85976), announced the availability of the guidance for industry entitled "Providing Post-marketing Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report)" to indicate its willingness to accept post-market periodic safety reports using the ICH PBRE format in lieu of the specific reports described in FDA regulations.

Because FDA regulations in §§ 314.80(c)(2) and 600.80(c)(2) include specific requirements for periodic safety reports, in order for an applicant to submit an alternative report, such as the PBRE, for a given product, FDA must grant a waiver. Existing regulations permit applicants to request waivers of any post-marketing safety reporting requirement, and the information collections associated with such waiver requests generally are approved under existing control numbers. (See § 314.90(a), waivers for drugs subject to NDAs and ANDAs, approved under OMB control number 0910-0001, and § 600.90(a), waivers for products subject to BLAs, approved under OMB control number 0910-0308.) The November 29, 2016, guidance both explains conditions under which applicants that have previously received waivers to submit reporting information in the format of the previous ICH guidance would be permitted to apply those existing waivers to the submission of PBREs, and also advises how applicants that have not previously obtained a waiver may submit waiver requests to submit the PBRE.

There are information collections proposed in the November 29, 2016, guidance that are related to waivers specifically to enable the submission of PBREs, and these information collections are not already addressed under the approved control numbers covering waiver submissions and periodic safety reports generally. FDA has previously granted waiver requests, submitted under §§ 314.90(a) and 600.90(a), that allow applicants to prepare and submit reports using the periodic safety update report (PSUR) format described in FDA's 1996 and 2004 ICH E2C guidance. In accordance with the recommendations of the November 29, 2016, guidance, if an applicant already has a PSUR waiver in place for a given approved application, FDA will consider the existing PSUR waiver to allow the applicant to submit

a PBRE instead of a PSUR because the PBRE replaces the PSUR for post-marketing periodic safety reporting for that application. The applicant would not need to submit a new waiver request unless the applicant wishes to change the frequency of reporting. FDA will consider requests to be waived of the quarterly reporting requirement but will not waive applicants of the annual reporting requirement.

If an applicant submits a PBRE in place of the PSUR and uses a different data lock point, the applicant should submit overlapping reports or submit a one-time PADER/PAER in order to cover the gap in reporting intervals. The applicant should submit notification to the application(s), indicating the change in data lock point and should include a description of the measures taken to ensure that there are no resulting gaps in reporting.

If an applicant submits a PBRE in place of the PSUR and uses a different reporting frequency for the PBRE than was used for the PSUR, the continued validity of the waiver will be conditioned on the submission of a PADER/PAER as needed to fulfill the reporting frequency requirement under FDA regulations. The applicant should submit a notification to the application(s), describing this change and the measures taken to ensure that the periodicity requirements are being met.

FDA expects approximately 187 waiver requests and notifications to include the additional information described previously in this document for using a different data lock point and/or for using a different reporting frequency when submitting a PBRE. FDA expects approximately 55 applicants to make these submissions, and we estimate that the time for submitting the additional information described previously would be on average approximately 1 hour for each waiver request or notification.

If an applicant does not have a PSUR waiver in place for an approved application, the applicant may submit a waiver request under § 314.90(a) or § 600.90(a) to submit a PBRE instead of the PADER/PAER. The applicant should submit a request to FDA for each approved application for which a waiver is requested, and a single waiver request letter can include multiple applications. Waiver requests should be submitted to each of the application(s) in the request, and may be submitted electronically or by mail as described in the November 29, 2016, guidance. Each

PBRE waiver request should include the following information:

- The product name(s) and application number(s);
- a brief description of the justification for the request;
- the U.S. approval date for the product(s) and current reporting interval used;
- the reporting interval of the last PADER/PAER submitted for the product(s); and
- the data lock point that will be used for each PBRE. If a data lock point other than one aligned to the U.S. approval date is proposed, the applicant should describe how he/she will ensure that there are no gaps in reporting intervals (e.g., by submitting overlapping reports; submitting a one-time PADER/PAER to cover the gap period; or, if the gap is less than 2 months, extending the reporting interval of the final PADER/PAER to close the gap).
- The frequency for submitting the PBRE, as described in section IV.C of the April 8, 2013, draft guidance.
- The email address and telephone number for the individual who can provide additional information regarding the waiver request.

As explained earlier, existing regulations at § 314.90(a) or 600.90(a) permit applicants to request waivers of any post-marketing safety reporting requirement, and the information collections associated with such waiver requests generally are approved under OMB control numbers 0910-0001 and 0910-0308. FDA believes that the information submitted under numbers 1-4 and number 7 in the list in the previous paragraph is information that is typical of any waiver request regarding post-marketing safety reporting and is accounted for in the existing approved collections of information for waiver requests and reports. Concerning numbers 5 and 6, FDA expects approximately 67 waiver requests to include the additional information for using a different data lock point and/or for using a different reporting frequency when submitting a PBRE. FDA expects approximately 29 applicants to make these submissions, and we estimate that the time for submitting the additional information described in the previous paragraph would be on average approximately 2 hours for each waiver request.

FDA estimates the additional burden of this collection of information as follows:

TABLE 1—ESTIMATED REPORTING BURDEN<sup>1</sup>

Additional information and/or notifications for using a different data lock point and/or a different reporting frequency	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Applicants that have a PSUR waiver for an approved application .....	55	3.4	187	1	187
Applicants that do not have a PSUR waiver for an approved application .....	29	2.3	67	2	134
Total .....	.....	.....	.....	.....	321

<sup>1</sup> There are no capital or operating and maintenance costs associated with the information collection.

Dated: May 18, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2014–N–0222]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry—User Fee Waivers, Reductions, and Refunds for Drug and Biological Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on recommendations to applicants considering whether to request a waiver or reduction in user fees.

**DATES:** Submit either electronic or written comments on the collection of information by July 24, 2017.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov/>. Follow

the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov/> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov/>. If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA–2014–N–0222 for "User Fee Waivers, Reductions, and Refunds for Drug and Biological Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov/> or at the Division

of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov/>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov/> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** JennaLynn Capezuto, Office of Operations, Food and Drug Administration, Three White Flint